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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,857	01/30/2004	David Lewis	248336US0DIV	3917

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,857	LEWIS ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-17 and 28-33 are pending. Applicants have cancelled claims 1-15 and 18-27. Receipt and consideration of Applicants' new IDS (submitted on July 18, 2006) as well as amended claims and arguments/remarks is acknowledged.

Specification

The objection of claim 16 because of the informalities described on page 2 of the previous office action mailed on January 18, 2006 **is withdrawn**, because Applicants' amendment to claim 16 corrected the informality.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 16, 17, and 33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, per Applicants' amendments to remove parentheses around claim limitations in claims 16 and 17. Claim 33 depends from claim 16.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 16-17, 29, and 31-33 under 35 U.S.C. 102(b) as being anticipated by McNally et al. (U.S. Patent No. 5,653,961) **is maintained** for the reasons of record set forth on pages 3-4 of the previous office action mailed on January 18, 2006. The rejection of claims 18-21, and 23-27 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over McNally et al. (U.S. Patent No. 5,653,961) is moot, because said claim has been cancelled.

The rejection of claims 28 and 30 under 35 U.S.C. 103(a) as being unpatentable over McNally et al. (U.S. Patent No. 5,653,961) in view of Byron et al (U.S. Patent No. 5,190,029) **is maintained** for the reasons of record set forth on pages 3-4 and 6-7 of the previous office action mailed on January 18, 2006.

The rejection of claims 16-24 and 27-32 under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (WO 98/34595; U.S. Patent No. 6,461,591 is the English language equivalent of WO 98/34595) **is withdrawn** per Applicants' amendment to claim 16 requiring an MMAD greater than 2 microns.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is

appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejections on the ground of nonstatutory obviousness-type double patenting of (1) claims 16-17 and 28-33 (all pending claims) as being unpatentable over claims 1-12, 14, and 16-29 of U.S. Patent No. 6,713,047; (2) claims 16-17 and 30-32 as being unpatentable over claims 1-14 and 22-24 of U.S. Patent No. 6,964,759; and (3) claims 16-17, and 28-32 as being unpatentable over claims 11-44 of U.S. Patent No. 6,713,047 (formerly copending application 09/831,888) **are maintained** because Applicants' have requested to hold these rejections in abeyance until it is clear what material the Examiner deems patentable. The specific rejected claims have been changed to reflect Applicants cancellation of claims 1-15 and 18-27.

Claims 16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, and 13 of copending Application No. 10/505,679 (copending '679; cited in Applicant's newly submitted IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Independent claim 16 of the instant

application claims an aerosol produced from a solution consisting of one or more solubilized active materials, a propellant consisting of HFA 227 and HFA 134a in a HFA 227: HFA 134a ratio ranging from 10:90 to 90:10, ethanol, and wherein the aerosol produced has an MMAD greater than 2 microns and at least 40% of said aerosol is composed of fine particles having a diameter of less than 4.7 microns. Independent claim 1 of copending '679 claims an aerosol pharmaceutical composition comprising a medicament, a mixture of HFA propellant, and one or more cosolvents, wherein upon actuation from an inhaler the aerosol particles have a particle size between 0.5 microns and 2.5 microns with a MMAD of about 1-2 microns and a fine particle fraction (FPF) of at least 30%. An MMAD of about 1-2 microns (e.g. 2.2 microns) reads on particles with an MMAD greater than 2 microns in which at least 40% of the particles have a size of less than 4.7 microns (i.e. a fine particle fraction of 40%). There is no upper limit on the FPF in claim 1 of copending '679. Subsequent dependent claims in copending '679 identify the cosolvent as being ethanol (claim 5 in copending '679) and the HFA propellants as being HFA 134a and HFA 227 (claim 4 in copending '679).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments, see page 6, filed July 18, 2006 with respect to the rejection of claims 16-24 and 27-32 under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (WO 98/34595; U.S. Patent No. 6,461,591 is the English language equivalent of WO 98/34595) have

been fully considered and are persuasive. The rejection of claims 16-24 and 27-32 under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (WO 98/34595; U.S. Patent No. 6,461,591 is the English language equivalent of WO 98/34595) has been withdrawn.

Applicant's arguments filed July 18, 2006 have been fully considered but they are not persuasive. Applicants' traversal of the rejections utilizing McNally (USPN 5,653,961) as the only or primary reference is based on the assertion that McNally fails to teach particles having an MMAD greater than 2 microns, wherein at least 40% of said particles have a diameter of less than 4.7 microns. The Examiner respectfully disagrees, because McNally discloses formulations in Examples 1-2 having a respirable fraction (i.e. the percent by weight of particles having an ***aerodynamic particle size less than 4.7 microns***) ranging from 45% to 69%. This disclosure meets the limitations of claim 16 concerning the physical characteristics of the aerosol particles (see page 4 of the previous office action mailed on January 18, 2006). Regarding the different amounts of HFA 134a and HFA 227 (P134a and P227 in McNally), it is emphasized that in Table 4, McNally discloses various ratios of HFA 134a to HFA 227 ranging from 0:100 to 100:0, which encompasses Applicants' claimed range of HFA 134a to HFA227 ratios.

Other Matter

It is noted that Applicants' have amended claim 16 to recite "consisting of" language, however, the use of open transitional language in dependent claims 28-30 effectively reopens the claim language for the entire composition claimed. If Applicants' wish to utilize "consisting of" claim language it is respectfully suggested that this language is incorporated in the claims depending from claim 16 as well.

Conclusion

Claims 16-17 and 28-33 are rejected. No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on July 18, 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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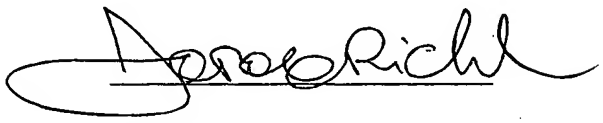

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